UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS OF ABBAS SHOBEIRI, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants") submit this memorandum in support of their motion to exclude certain opinions of Abbas Shobeiri, M.D.

INTRODUCTION

Dr. Shobeiri is a pelvic surgeon and urogynecologist in Oklahoma who has experience installing and removing sling systems and who has rendered substantially identical opinions on Defendants' TVT-O and Prolift devices.[1] (*See* Dr. Shobeiri curriculum vitae and Expert Report, attached as Exhibits B, C, and D). Plaintiffs, however, hope to elicit testimony from Dr. Shobeiri about topics that are entirely outside his professional education, training and experience and therefore outside his area of competence. Moreover, his general causation opinions are unreliable and largely irrelevant.

Specifically, the Court should preclude Dr. Shobeiri from testifying regarding:

[1] One plaintiff who was implanted with Defendants' Prosima device has designated Dr. Shobeiri as a general expert in her case. *See* Exhibit A. Dr. Shobeiri has not produced *any* expert reports on the Prosima device in this Wave, however, and he should therefore be excluded as an expert on Prosima in that case on this ground alone.

- Alleged design defects in the TVT-O and Prolift that are not supported by reliable scientific evidence and that he is not qualified to address.
- "Safer" alternative products whose comparative safety and efficacy have not been quantified.
- Alleged inadequate warnings that he is not qualified to address.
- Alleged inadequate training and education that is not relevant.
- Defendants' knowledge, state of mind or intent.

LEGAL ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014). The Supreme Court's decision in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), precludes "engagement of 'expert' witnesses whose intended role is more to argue the client's cause from the witness stand than to bring the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit." *In re: Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 538 (S.D.N.Y. 2004). Plaintiffs seek to do precisely that through the testimony of Dr. Shobeiri. While Dr. Shobeiri may be qualified to render opinions about pelvic surgery, he has no specialized knowledge or expertise that would substantially assist the jury as it relates to other areas.

Dr. Shobeiri opines that: 1) the TVT-O and Prolift were defectively designed; 2) there were safer alternatives to both products; 3) the warnings contained in the TVT-O and Prolift Instructions for Use (IFU) were inadequate; 4) the Defendants failed to adequately test the TVT-O and Prolift and doctors in the community were not aware of complications with both products; and 5) the Defendants were aware of the undisclosed risks of TVT-O. (Report of Dr. Abbas Shobeiri Regarding TVT-O ("TVT-O Rep.") at 6, 19, 22-24, 26, attached as Exhibit C; Report of

Dr. Abbas Shobeiri Regarding Prolift ("Prolift Rep.") at 6, 21-23, 25, 29, attached as Exhibit D). Each of these opinions is flawed and should be excluded.

I. Dr. Shobeiri's Opinion That The TVT-O And Prolift Are Defectively Designed Is Unreliable.

"Expert opinions premised upon speculation and conjecture are insufficient to create a genuine issue of material fact to survive summary judgment." *Dana Corp. v. Am. Standard, Inc.*, 866 F. Supp. 1481, 1499 (N.D. Ind. 1994). An expert's simple *ipse dixit* is insufficient to establish a matter; rather, the expert must explain the basis of his statements to link his conclusions to the facts. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999); *Hines v. Wyeth*, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011).

Dr. Shobeiri opines that the TVT-O and Prolift are defectively designed because their polypropelene mesh can shrink, contract, or deform; in his deposition, Dr. Shobeiri elaborated that this alleged defect is that the mesh can coil, rope, and fray. (TVT-O Rep. at 22-23; Prolift Rep. at 18-19; Feb. 27, 2016 Dep. of Abbas Shobeiri, M.D. on TVT-O ("2/27/16 Dep.") at 107:1-19, attached as Exhibit E (Q: "Tell me what specifically about the design you're critical of." A: "Well, the fact that [it] coils. [It] ropes. It doesn't stay flat. The way the fact that it has edges that fray, you know. Those are the design flaws."). Dr. Shobeiri admits, however, that these issues are not exclusive to Defendants' products. (2/27/16 Dep. at 107:2-109:17; 132:5-133:10). Moreover, his opinions regarding these supposed defects are not based on any reliable methodology but are instead mere *ipse dixit.* Furthermore, Dr. Shobeiri lacks the requisite expertise to opine regarding certain characteristics of the TVT-O and Prolift products.

Dr. Shobeiri is neither qualified to opine, nor does he have evidence to support, any opinion addressing the biocompatibility characteristics of the mesh used in the TVT Secur. Although Dr. Shobeiri is a skilled physician, he is not an expert in biocompatibility issues. He is

admittedly not an expert in synthetic sling design, nor is he a biomaterials expert. (2/27/16 Dep. at 30:16-31:2; 136:1-3). His lack of expertise in this area necessarily impacts the permissible scope of his testimony.

Nevertheless, Dr. Shobeiri makes sweeping statements in his reports that "[i]n a woman presenting with groin pain and/or vaginal/mesh pain and sexual pain following insertion of the TVT-O device, a device-related condition is, more likely than no, the most likely diagnosis," and "[i]n a woman presenting with groin pain and/or vaginal/mesh pain and sexual pain following placement of the TVT-O device, these symptoms are, more likely than not, associated with the material . . . flaws of the TVT-O." (TVT-O Rep. at 5; *see also* Prolift Rep. at 6; TVT-O Rep. at 14 ("Symptoms of *suspected* vaginal mesh complications include vaginal discharge and/or bleeding, dyspareunia, pelvic pain, and recurrent urinary tract infections." (emphasis added); *id.* at 21 ("When a patient presents with vaginal pain and sexual pain following a mesh procedure, this condition, *more likely than not*, is caused by mesh and, *more likely than not*, is mediated by one or more of the mechanisms discussed in this report." (emphases added)). Yet, when questioned regarding these opinions in his deposition, Dr. Shobeiri could not identify any particular study supporting them. (2/27/16 Dep. at 101:16-106:13). He therefore has no reliable basis to opine that the alleged defects in mesh "more likely than not" cause the symptoms he describes.

Dr. Shobeiri cites no studies for his opinions that mesh contracts and fails to identify which part, precisely, of the TVT-O is defectively designed. (TVT-O Rep. at 22). He also failed to explain his methodology of determining that mesh ropes/rolls, frays, and curls. (2/27/16 Dep. at 108:19-109:12). He cites no scientific studies, peer-reviewed or otherwise, to support his speculative criticisms. Because he cites no supporting literature, and his opinions are

conclusory, speculative and unsupported by evidence. Such testimony is not helpful to the jury and should be excluded.

II. Dr. Shobeiri's Opinions That There Were Safer Alternative Products Are Subjective And Unreliable.

In the present case, Dr. Shobeiri opines that there were other equally or more-effective alternative products to treat the conditions that TVT-O and Prolift were designed to treat. (TVT-O Rep. at 6, 26; Prolift Rep. at 6, 27-28). In particular, he opines that retropubic devices were safer than transobturator slings (2/27/16 Dep. 109:24-111:20), and that it is safer to implant mesh using abdominal or laparoscopic sacrocolpopexy than using Prolift products (Prolift Rep. at 27-28).

Dr. Shobeiri has no basis to support these conclusions. He did not disclose any testing, calculations, engineering analysis, or publications that supported his opinions. In fact, he admits that the medical literature states that the TVT-O is equivalent to retropubic devices when it comes to safety and efficacy. (2/27/16 Dep. at 111:21-112:14). Furthermore, abdominal or laparoscopic sacrocolpopexy is an alternative procedure or technique, not an alternative design or product. Any alleged comparative benefits of traditional surgical approaches to treat SUI or POP are not even relevant to Plaintiffs' design defect claims, because they are not medical devices. As noted in *Hines v. Wyeth*, 2011 WL 1990496, at *8 (S.D. W. Va. May 23, 2011):

> [A]n "alternative design must not be an altogether essentially different product." *Torkie*, 739 F. Supp. 2d at 900. Stated differently, "an alternative design is not reasonable if it alters a fundamental and necessary characteristic of the product." *Id.*; *see also Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995) (noting, in design defect context, that "[a] motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle."); *Kimball v. RJ Reynolds Tobacco Co.*, No. C03–664, 2006 WL 1148506, *3 (W.D. Wash. Apr. 26, 2006) (holding that a plaintiff "cannot point to an entirely different product as an alternative design").

See also Caterpillar, Inc., 911 S.W.2d at 385 (finding that the law of product liability does not "impose liability in such a way as to eliminate whole categories of useful products from the market"). Although in *Hines*, the Court indicated that this presented a jury question, here no reasonable mind could conclude that traditional surgical approaches are products.

The notion that traditional surgical procedures are safer alternatives to Ethicon's devices is premised on the assumption that all mesh products are unsafe. Such an "argument . . . really takes issue with the choice of treatment made by [the patient]'s physician, not with a specific fault of" the TVT device. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) (surgical alternative to pedicle screw could not be considered). As noted in *Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013), "non-mesh repair is not an alternative design and does not meet Plaintiff's burden to support" a design-defect claim. In reality, Plaintiffs takes issue with the choice of their physicians in recommending a medical device (ie. TVT) rather than a non-medical device (ie. autologous slings).

The first *Daubert* factor is whether the theory or technique employed by the expert can be and has been tested. *Daubert*, 509 U.S. at 591-95; *see Watkins v. Telsmith, Inc.*, 121 F.3d 984, 992 (5th Cir. 1997) (proposing alternative design requires more than "conceptualizing possibilities"); *see also Oglesby v. Gen. Motors Corp.*, 190 F.3d 244 (4th Cir. 1999) (affirming exclusion of mechanical engineer's expert testimony where "he did not know the type or composition of the plastic" at issue, failed to ask the manufacturer, analyze or test the part, and did not apply any calculations). Dr. Shobeiri has failed to satisfy that factor here with respect to safer alternative designs.

Further, Dr. Shobeiri's reports and testimony do not link his conclusions to the analysis, if any, that he performed to determine that these other products or techniques are indeed more effective. His theories rely heavily upon his own subjective interpretation, and have not been generally accepted within the relevant scientific community. *See Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 311 (2d Cir. 2008) (rejecting expert's conclusory statement where it was not accompanied by "any evidentiary citation" or followed by any elaboration of the expert's reasoning); *Hudgens v. Bell Helicopters/Textron*, 328 F.3d 1329, 1344 (11th Cir. 2003) ("[A]n expert's failure to explain the basis for an important inference mandates exclusion of his or her opinion."). This Court has previously excluded opinions of safer alternative designs where the expert fails to cite to studies supporting his opinion. *See Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Order at 16-17 (S.D. W. Va. Nov. 20, 2014) (excluding testimony of Dr. Uwe Klinge where "[i]n the section of his report specifically addressing alternative design, Dr. Klinge fails to cite *any* peer-reviewed studies" (emphasis in original)) (attached hereto as Exhibit F). Therefore, Dr. Shobeiri's opinion that safer alternative products exist is unreliable and should be excluded.

III. This Court Should Exclude Dr. Shobeiri's Opinions Regarding The Adequacy Of The TVT-O And Prolift IFUs.

Dr. Shobeiri contends that the IFUs which accompanied the TVT-O and Prolift were defective and failed to provide adequate warnings and information to treating surgeons. TVT-O Rep. at 6, 23-24; Prolift Rep. at 6, 22, 25. He contends that the IFUs failed to apprise physicians of the severity, frequency, and permanence of risks. TVT-O Rep. at 23-24; Prolift Rep. at 22-23. These opinions should be excluded on several grounds.

First, Dr. Shobeiri has no expertise in medical-device warnings or regulatory requirements.

Second, he fails to identify any reliable scientific evidence establishing that degree of the warnings made them inadequate. His opinions are nothing more than subjective *ipse dixit*, which is unreliable, inadmissible, and should be excluded.

A. Dr. Shobeiri is not qualified to testify about product warnings.

Because Dr. Shobeiri is not a biomaterials expert, as discussed *supra*, he is not qualified to testify to the adequacy of warnings regarding biomaterial characteristics related to mesh allegedly roping, curling, or fraying. Dr. Shobeiri should not be allowed to testify about failure to warn of alleged design defects he is not competent to identify. In other mesh litigation, the proffered experts' qualifications to opine about biomaterial properties such as degradation and porosity have been closely scrutinized and such testimony has been limited to experts with extensive biomaterial and biomechanical engineering education and experience. *See In re C.R. Bard, Inc., Pelvic Repair Sys. Liab. Litig.*, 948 F. Supp. 2d 589, 623 (S.D. W. Va. 2013) (allowing physician testimony regarding biomechanical analysis of mesh only after establishing that physician had two engineering degrees, had practiced as an engineer for twelve years, and had focused on studying biomechanical analysis of pelvic floor structures and the pelvic floor from an engineering perspective for ten years); *id.* at 633 (expressing "concerns about [physician's] qualifications to testify specifically as to the properties of polypropylene" mesh, but allowing testimony only after establishing that physician not only had a biomedical engineering degree, but also routinely evaluated biomaterials, developed new biomaterials and modified existing biomaterials, and had specific experience with polymeric material).

Moreover, Dr. Shobeiri is not otherwise qualified to testify regarding the adequacy of the warnings accompanying the TVT-O and Prolift because he has absolutely no expertise in that area. Dr. Shobeiri has no demonstrated or identified experience in preparing IFU documents and

no training related to developing warnings or labeling. 2/27/16 Dep. at 36:7-38:11. He admits that he is not a FDA regulatory expert. *Id.* at 31:3-17. His experience as a urogynecologist and surgeon is not sufficient to inform his opinions regarding the highly regulated area of prescription drug labeling and warnings. *See Cisson v. C.R. Bard, Inc.*, 948 F. Supp.2d 589, 611 (S.D. W. Va. 2013) (excluding plaintiff's expert, Dr. Bob Shull, on warnings and labels for medical devices: "[d]espite his stellar qualifications as a urogynecologist, Dr. Shull is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process."); *Tyree v. Boston Scientific Corp.*, 2014 WL 5486694, at *36-37 (S.D. W. Va. Oct. 29, 2014) (Dr. Donald Ostergard (urogynecologist), although qualified to opine on the design of the sling in question, was not qualified to opine on product warnings and FDA compliance); *Free v. Bondo-Mar-Hyde Corp.*, 25 Fed. App'x 170 (4th Cir. 2002) (affirming the exclusion of testimony because highly credentialed expert nevertheless lacked knowledge of specific matters essential to subject of his opinion)**.**

Because Dr. Shobeiri is not qualified to opine regarding the adequacy of the TVT-O and Prolift IFUs, his opinions as to a failure to warn about alleged defects in those IFUs should be excluded.

B. Dr. Shobeiri does not identify a reliable basis for his opinions.

As an alternative ground for exclusion, Dr. Shobeiri expert reports dos not set forth a reliable basis for his opinions that the TVT-O and Prolift IFUs are inadequate. He faults the IFUs for not going into great detail about the frequency and permanence of the risks, but does not dispute that the TVT-O IFU warns of extrusion, erosion, inflammation, infection, and urinary tract obstruction, and the Prolift IFU warns of inflammation, erosion, extrusion, and other risks. (TVT-O Rep. at 24; Prolift Rep. at 12, 23). In fact, Dr. Shobeiri believes that mesh sling

surgeries "are the standard for the treatment of stress urinary leakage." 2/27/16 Dep. at 40:4-9. He admits that the American Urogynecology Society and American College of Gynecologists share that position. 2/27/16 Dep. at 40:11-15. Simply because the IFUs do not use the "magic language" Dr. Shobeiri would prefer does not make them inadequate, and Dr. Shobeiri has not cited scientific evidence showing otherwise. He relies only on his own experience reviewing IFUs "for many other medical products throughout [his] career." (Prolift Rep. at 23). This Court has excluded expert opinions that were based only on clinical experience without any "basis in reliable methodology." *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 606 (S.D. W. Va. 2013) (excluding testimony of Dr. Dean Altenhofen). The Court should do the same in this instance.

IV. Dr. Shobeiri's Opinions Regarding Inadequate Education Or Training Are Not Relevant And Opinions Regarding Failure To Test Are Not Supported By A Reliable Methodology.

Dr. Shobeiri opines that "[t]imely recognition and referral of mesh complications is of utmost importance to prevent prolonged suffering of patients," and that "complications are under-appreciated by community doctors and often results in a delay of appropriate treatment." (Prolift Rep. at 6, 21; *see also* TVT-O Rep. at 5-6, 22). He also opines that "Ethicon's physician training program for the Prolift program was inadequate." (Prolift Rep. at 30). Although Dr. Shobeiri opines that Defendants failed to provide adequate training and opines that "community doctors" were not aware of the risks of mesh, he never explicitly states that Defendants had the responsibility to educate "community doctors" and cites only one study that he was involved in confirming this opinion (2/27/16 Dep. at 137:12-138:14). The study found that 75 percent of patients with mesh complications were self-referred, as opposed to referred for care by the implanting physician. (2/27/16 Dep. at 141:15-17). He admits that in 2008, the FDA issued a report alerting the medical community of complications associated with mesh. (2/27/16 Dep. at

139:11-140:4). He also admits that the study made no effort to determine whether the patients' mesh was implanted before or after the 2008 FDA report. (2/27/16 Dep at 142:3-10). The only study on which Dr. Shobeiri relies for the proposition that doctors in the community were uninformed about the potential complications of mesh is thus not reliable because it fails to account for the possibility that the patients' doctors had not received the 2008 FDA report.

Furthermore, Dr. Shobeiri's testimony contradicts his opinion that doctors in the community were uninformed about the potential complications of mesh. Dr. Shobeiri testified that, before implanting a product, he would expect other doctors sharing his specialty to review the medical literature and review the IFUs. (2/27/16 Dep. at 114:4-19). He also stated that the medical literature has long stated that mesh contracts. (2/27/16 Dep. at 78:17-79:23). If physicians in the community are expected to review the IFU and the medical literature, both of which warn about complications with mesh, Dr. Shobeiri has no basis for opining that doctors in the community were uninformed about the complications of mesh. *See Sanchez v. Bos. Sci. Corp.*, No. 2:12–cv–05762, 2014 WL 4851989, at *14 (S.D. W. Va. Sept. 29, 2014) (excluding opinion where "Dr. Margolis's inconsistencies [in contradicting himself in his deposition] seem to directly shed light on the unreliability of his method"). To the extent that Dr. Shobeiri faults Ethicon for their being uninformed or failing to train, Dr. Shobeiri has cited no evidence demonstrating that Ethicon had an obligation to train. Dr. Shobeiri's opinion that Ethicon failed to provide adequate training is therefore not relevant.

Dr. Shobeiri also opines that Ethicon should have "conduct[ed] clinical studies to determine whether naturally occurring conditions in the pelvis and vagina could cause the polypropylene mesh to degrade." (Prolift Rep. at 29). But he fails to explain his reasoning or his methodology for this opinion. The opinion should therefore be excluded. *See, e.g., Lewis v.*

Ethicon, Inc., No. 2:12-cv-4301, 2014 WL 186872, at *18 (S.D. W. Va. Jan. 15, 2014) (excluding opinion of Dr. Peggy Pence regarding Ethicon's alleged failure to conduct appropriate tests on the TVT because it was mere *ipse dixit*, unsupported by any particular regulations or authorities). Additionally, instead of relying upon any particular expertise to opine regarding Ethicon's training program and alleged failure to test, Dr. Shobeiri merely regurgitates information contained in internal Ethicon documents. (Prolift Rep. Rep. at 29,30). Such narrative testimony should be excluded as Dr. Shobeiri would merely be serving as "Plaintiffs' advocate rather than expert." *In re: Trasylol*, 709 F. Supp. 2d 1323, 1346-47 (S.D. Fla. 2010); *accord In re: Rezulin*, 309 F. Supp. 2d at 546 (excluding expert testimony intended merely to "provid[e] an historical commentary of what happened"); *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005) (stating that "an expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence" and excluding expert's testimony, including expert's references to defendant's internal documents; *In re: Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (excluding portions of an expert's report because it "presents a narrative of select regulatory events through the summary or selective quotation from internal Merck documents, regulatory findings, and the deposition testimony of Merck employees").

V. The Court Should Exclude Dr. Shobeiri's Opinions About Ethicon's Knowledge, State Of Mind, Or Bad Acts.

The Court should preclude Dr. Shobeiri from testifying about Ethicon's alleged knowledge and bad acts. For instance, Dr. Shobeiri states that "Ethicon knew that the TVT-O was associated with more pain than other slings;" that Ethicon "did not consider physician training to be a priority, or even a necessity;" and that "Ethicon[] [knew] about the risks inherent in the design of its products which Ethicon's internal documents specifically recognize." (TVT-

O Rep. at 19; Prolift Rep. at 30). There is nothing about Dr. Shobeiri's experience as a urogynecologist that affords him specialized knowledge or clairvoyance to testify about what Ethicon did or did not know or to speculate about what Ethicon supposedly never did. *See, e.g.*, *In re: Diet Drugs Prods. Liab. Litig.*, 2000 U.S. Dist. LEXIS 9037, at *9 (E.D. Pa. 2000) (precluding the plaintiffs' experts from testifying as to the defendants' intent); *In re: Rezulin*, 309 F. Supp. 2d at 547 ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony"); *BorgWarner, Inc. v. Honeywell Int'l, Inc.*, 750 F. Supp. 2d 596, 611 (W.D.N.C. 2010) (precluding a party's expert witness from opining about a party's intent). To the extent that Dr. Shobeiri's opinions are based on his review of documents that Plaintiffs' counsel selectively presented to him, *see* 2/27/16 Dep. at 46:11-48:14, these concern mere "lay matters which a jury is capable of understanding and deciding without the expert's help." *Andrews v. Metro N. Commuter R.R. Co.*, 882 F.2d 705, 708 (2d Cir. 1989).

Recently, this Court precluded another physician from offering similar testimony. In *Lewis v. Ethicon*, No. 12-cv-4301, 2014 WL 186872, (S.D. W. Va. Jan 15, 2014), this Court found that "expert opinions on Ethicon's knowledge or state of mind are not helpful to the jury" and that although the expert in issue was "qualified as a physician; he is not qualified by 'knowledge, skill, experience, training or education' to opine on Ethicon's state of mind or knowledge." *Id.* at *15. And in *In re: C.R. Bard, Inc.*, 948 F. Supp. 2d 589 (S.D. W. Va. 2013), one of the plaintiffs' experts, Dr. Bob Shull, a urogynecologist like Dr. Shobeiri, intended to testify about "Bard's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics." *Id.* at 610. This Court, however, found as follows:

> While an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions – assuming the opinions are otherwise admissible – Bard's knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are

> not appropriate subjects of expert testimony because opinions on these matters will not assist the jury. *See, e.g.*, *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony . . . the question of intent is a classic jury question and not one for the experts.") (internal quotation marks omitted); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (precluding testimony as to "the knowledge, motivations, intent, state of mind, or purposes of" a company and its employees because it "is not a proper subject for expert or even lay testimony"). Accordingly, I FIND that Dr. Shull's opinions related to Bard's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics should be excluded.

Id. at 611 (emphasis added); *see also Hershberger v. Ethicon Endo-Surgery, Inc.*, 2012 WL 52444287, at *7-8 (S.D. W. Va. Feb. 15, 2012) (Johnston, J.) (excluding an expert from testifying as to product defect, where expert's opinion was not based on his experience or education, but rather was based on other experts' testimony and the defendant's corporate documents).

For the same reasons that this Court precluded Dr. Shull from testifying about such matters, the Court should also preclude Dr. Shobeiri from testifying about these matters.

CONCLUSION

For the reasons set forth above, the Court should limit the parameters of Dr. Shobeiri's testimony consistent with the foregoing.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 21, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
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